DETAILED ACTION

The response filed on 8/4/08on presents remarks and arguments to the office action mailed 4/15/08. Applicants' request for reconsideration of the rejection of claims in the last office action has been considered.

Applicants' arguments, filed have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Status of Claims

Claims 21-25 are now pending. Claims 1-20 are cancelled.

Withdrawn Claim Rejections - 35 USC § 112

Applicant's remarks are considered and the rejection is withdrawn.

Claims 21-25 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating cancer, does not reasonably provide enablement for effective amount for preventing cancer is withdrawn.

Maintained Claim Rejections - 35 USC § 103

Applicant's argument:

Applicant argues that the showing of unexpected results should overcome the claimed rejection. The unexpected result is shown in Tables 1, 3-5 and 7 of the specification. Applicant states that when mice were treated with compound 1 in

combination with various known antineoplastic agents, such as docetaxel, 5-FU, doxorubicin, cisplatin and irinotecan synergistic effect was seen in the treatment.

Examiners response:

Careful consideration has been given to the synergistic effects and/or unexpected results however, the claimed unexpected result is found not persuasive because:

The claims recite “a method of treating a human” by administering compound 5-(5-fluoro-2-oxo 1, 2 dihydroindol-3-ylidenemethyl) -1H-pyrrole-3-carboxylic acid (2-diethylaminoethyl) amide with a combination of at least one chemotherapeutic agent, wherein the cancer is breast, lung or colon cancer.

"The evidence relied upon also should be reasonably commensurate in scope with the subject matter claimed and illustrate the claimed subject matter "as a class" relative to the prior art subject matter.”

The examples show specific therapeutic effective amounts for a synergistic effect or additive effect, whilst the claims do not contain any such therapeutic effective amounts. Next, the claims recite treating a ‘human”, the synergistic effect is in an animal model, there is no showing of the correlation from the animal model to a human. It is a known fact in the scientific environment that human disease is strongly relied upon the use of in vivo animal models however drug efficacy does not often translate effectively to human conditions. The effective amount that showed synergistic effect may not be capable of treating or delaying cancer in a human. In the Goodman and Gilman reference, it explicitly states that drugs are generally more effective and may be

synergistic through biochemical interactions, especially if the drugs do not share a common mechanism, see page 1230 of Goodman et al (of record). Thus unexpected synergism would be expected in the combination as taught by Goodman et al. Also, the unexpected results are not commensurate in scope with the claims, that are drawn to treating various forms of cancer, breast, lung and colon in combination with diverse chemotherapeutics, and there is no showing that the unexpected result would hold true to show a trend that would suggest an unexpected result commensurate in scope with the claims.

Applicant's arguments have been fully considered but they are not persuasive. The rejection is maintained as in the last office action of record.

Claims 21-25 remain rejected under 35 U.S.C. 103(a) as being obvious over Tang et al., US 6573293 (already of record) and/or Hawley et al, US2003/0069298 (IDS) in view of Goodman and Gilman, Pharm. 9th Ed. Pharmacological Basis of Therapeutics.

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHIRLEY V. GEMBEH whose telephone number is (571)272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL HARTLEY can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/S. V. G./
Examiner, Art Unit 1618
10/16/08